



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Choi et al.

Serial No. : 09/831,929 Examiner : L. Channavajjala

Filed : June 29, 2001 Group Art Unit : 1615

For : BIOCIDE COMPOSITION AND STERILIZATION METHOD
USING THE SAME

**DECLARATION OF KI-SEUNG CHOI
UNDER 37 C.F.R. § 1.132**

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Peter J. Shen

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Attorney Name

PTO Registration No.

[Signature]

10/30/03

Date of Signature

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, KI-SEUNG CHOI, hereby declare as follows:

1. I am a co-inventor of the invention disclosed and claimed in the above-captioned United States patent application.

2. I am an employee of SK Chemicals Co., Ltd., which is the assignee of the rights, title and interest in the United States of the invention disclosed and claimed in the above-captioned United States patent application.

3. I am a named inventor or co-inventor of several inventions disclosed and claimed in United States patents and patent applications.

4. I have reviewed the Office Action dated June 30, 2003 by the U.S. Patent and Trademark Office for the above-captioned patent application together with U.S. Patent No. 5,278,178 to Hsu (hereinafter "Hsu"), Soviet Union Patent No. 1687261 to Gembitskii et al. (hereinafter "Gembitskii"), and Japanese Patent No. 10175809 by Toshimasa (hereinafter "Toshimasa"), all of which were discussed therein.

5. Hsu discloses antimicrobial and biocidal compositions comprising an isothiazolone and one or more commercial biocides for control of microorganisms in various industrial systems. Hsu does not disclose the biocide composition of the present patent application where the composition comprises 3-isothiazolone and polyhexamethyleneguanidine phosphate.

6. Gembitskii discloses the use of polyhexamethyleneguanidine gluconate as an active component in a disinfecting composition.

7. Toshimasa discloses a bactericidal composition for industrial use where polyhexamethylenebiguanidine hydrochloride is included as one of the active ingredients.

8. Claims 8-22 now pending in our patent application require polyhexamethyleneguanidine phosphate together with 3-isothiazolone to make the instantly claimed biocide compositions and use the instantly claimed sterilization methods.

9. The difference, in the presence of 3-isothiazolone, between the antibiotic abilities of polyhexamethyleneguanidine phosphate and that of polyhexamethyleneguanidine gluconate or polyhexamethylenebiguanidine hydrochloride reflects a fundamental difference between the disclosure of Gembitskii or Toshimasa, and the instantly claimed invention. The difference in the antibiotic abilities of each of these compounds can be determined by comparing the minimum inhibitory concentration (MIC) of each compound necessary for inhibiting certain microorganisms.

10. Under my direction and control, the following experiments were conducted. The antibiotic abilities of polyhexamethyleneguanidine phosphate and that of polyhexamethyleneguanidine gluconate or polyhexamethylenebiguanidine hydrochloride were compared, in the presence of 3-isothiazolone, by determining the minimum inhibitory concentration (MIC) in parts per million of each compound necessary to inhibit the growth of various microorganisms. These experiments were conducted in the same manner described in the Examples section of the present patent application, beginning at page 7, line 7 of the specification and continuing through page 9, line 17. Generally, the MIC of each compound was determined by visually observing with the naked eye the growth of microorganisms on the basis of "muddiness" of the solution.

11. When testing was performed to compare the antibiotic abilities of polyhexamethyleneguanidine phosphate, polyhexamethyleneguanidine gluconate, and polyhexamethyleneguanidine hydrochloride, in the presence of 3-isothiazolone, the following results were obtained:

Comparison of Minimum Inhibitory Concentration (“MIC”) Values Obtained From Biocides Using Polyhexamethyleneguanidine phosphate and Gluconate Salts of Polyhexamethyleneguanidine (“PHMG”) and Chloride Salts of Polyhexamethylenebiguanidine (“PHMBG”) in the Presence of Isothiazolone (“ITO”).

MICROBE	ITO + PHMG-H ₃ PO ₄ (instant invention)	ITO + PHMG-Cl (Hsu + Toshimasa)	ITO + PHMG-Gluconate (Hsu + Gembitskii)
<i>Bacillus subtilis</i>	32	32	32
<i>Salmonella typhimurium</i>	64	64	64
<i>Pseudomonas aeruginosa</i>	64	64	64
<i>Penicillium citrinum</i>	128	512	512
<i>Proteus vulgaris</i>	32	128	256
<i>Staphylococcus aureus</i>	64	64	64
<i>Candida albicans</i>	32	32	64
<i>Rhizopus oryzae</i>	64	64	64
<i>Aspergillus niger</i>	64	128	128

12. As seen in the table above, when polyhexamethyleneguanidine phosphate (in accordance with the present invention) was used in the presence of 3- isothiazolone, the MIC required to inhibit growth of the tested microorganisms generally was significantly lower than the MIC required to inhibit growth of the same microorganisms when polyhexamethyleneguanidine gluconate (disclosed by Gembitskii) or polyhexamethylenebiguanidine hydrochloride (disclosed by Toshimasa) was used. In fact,

the phosphate salt was often at least twice as effective as the hydrochloride salt (*see, e.g., Penicillium citrinum, Aspergillus niger*) or gluconate salt (*see, e.g., Penicillium citrinum, Aspergillus niger*). Indeed, the results demonstrate that, in the presence of 3-isothiazolone, the phosphate salt was more effective than the hydrochloride salt (*see Penicillium citrinum*) or gluconate salt (*see Proteus vulgaris*) in certain instances.

13. These results show that the overall antibiotic ability of polyhexamethyleneguanidine phosphate is surprisingly and unexpectedly greater than the antibiotic ability of either polyhexamethyleneguanidine gluconate or polyhexamethylenebiguanidine hydrochloride.

14. These results also demonstrate unpredictability in the comparative antibiotic activities of polyhexamethyleneguanidine-based compounds in the presence of 3-isothiazolone, such that one of ordinary skill in the art at the time of filing of the instant application would not reasonably expect the same antibiotic effect using any of the possible salts of polyhexamethyleneguanidine.

15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of any patent issuing from the above-captioned patent

application.

Sep. 29th, 2003

Date

K. S. Choi

KI-SEUNG CHOI